# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	) MDL NO. 1456 ) Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	) ) Judge Patti B. Saris
The City of New York v. Abbott Laboratories, Inc., et al. (S.D.N.Y. No. 04-CV-06054)	, ) )
County of Albany v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00425)	) )
County of Allegany v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06231)	) )
County of Broome v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00456)	) )
County of Cattaraugus v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06242)	) )
County of Cayuga v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00423)	) )
County of Chautauqua v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06204)	) ) )
County of Chemung v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06744)	
County of Chenango v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00354)	
County of Columbia v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00867)	

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IVAX CORPORATION'S AND IVAX PHARMACEUTICALS, INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO REVISED FIRST AMENDED CONSOLIDATED COMPLAINT

County of Cortland v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00881)  County of Dutchess v. Abbott Laboratories, Inc., et al. (S.D.N.Y. No. 05-CV-06458)  County of Essex County v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00878)  County of Fulton v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00519)  County of Genesee v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06206)  County of Greene v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00474)  County of Herkimer v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00415)  County of Jefferson v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00715)  County of Lewis v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00839)  County of Madison v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00714)  County of Monroe v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 04-CV-5126)  County of Niagara v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06296)  County of Oneida v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-00489)  County of Oneida v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-00489)  County of Onondaga v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-06373)  County of Orange v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06373)  County of Orleans v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06371)  County of Putnam v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06371)  County of Putnam v. Abbott Laboratories, Inc., et al.		
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County of Westchester v. Abbott Laboratories, Inc., et al. (S.D.N.Y. No. 03-CV-6178)	)
County of Wyoming v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 03-CV-6379)	)
AND	į́
County of Yates v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06172)	)

Defendants Ivax Corporation ("Ivax Corp.") and Ivax Pharmaceuticals, Inc. ("IPI"), by and through their attorneys, hereby state as an Answer and Affirmative Defenses to the Revised First Amended Consolidated Complaint, dated October 5, 2001, as follows:

## **PRELIMINARY STATEMENT**

The Revised First Amended Consolidated Complaint ("RFACC") improperly and repetitively refers to Ivax Corp. and IPI and certain other defendants and third persons, entities, or parties on a collective basis, failing to plead with requisite particularity allegations against Ivax Corp. and IPI or other defendants or third parties. Intentionally ambiguous pleading is improper and insufficient to apprise Ivax Corp. and IPI in any meaningful sense of the allegations asserted against them. Ivax Corp. and IPI have nevertheless attempted to respond to plaintiffs' allegations to the extent possible under the circumstances. To the extent allegations refer to the knowledge, conduct or actions of other defendants or entities, Ivax Corp. and IPI are generally without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Ivax Corp. and IPI deny those allegations. In answering the RFACC, Ivax Corp. and IPI respond only for themselves, even when the plaintiffs' allegations refer to alleged conduct by Ivax Corp. and IPI and other persons or entities.

The RFACC contains purported quotations from a number of sources. In answering allegations consisting of quotations, failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

The RFACC also improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond to it meaningfully. Many of the allegations of the

RFACC are vague or conclusory. In addition, the RFACC includes terms which are undefined and which are susceptible to different meanings.

Ivax Corp. and IPI explicitly deny the existence of, or its participation in, any fraud or fraudulent scheme. Ivax Corp. and IPI further deny each and every allegation contained in the RFACC, except as specifically admitted herein, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendoes or speculations which are contained in any averment or in the RFACC as a whole. Moreover, Ivax Corp. and IPI specifically deny any allegations contained in headings or exhibits in the RFACC.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

#### SPECIFIC RESPONSES

To the extent that the unnumbered paragraph immediately following the Table of Contents (the "Complaint's Introductory Paragraph") makes allegations against Ivax Corp. and/or IPI, Ivax Corp. and IPI deny them, except admit that the City of New York and certain New York Counties (collectively, the "Counties" or "plaintiffs") have made allegations against a number of defendants, including Ivax Corp. and IPI, as set forth in the RFACC. To the extent that the RFACC's Introductory Paragraph states legal conclusions, no response is required. To the extent the allegations of the RFACC's Introductory Paragraph are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore deny them on that basis.

1. Ivax Corp. and IPI admit that the Counties seek to bring this action as alleged in Paragraph 1 of the Complaint, but deny there is any basis for them to do so and deny that they

are entitled to any relief. Ivax Corp. and IPI also admit that Exhibit B to the RFACC purports to identify the prescription drugs at issue in this matter, but deny any liability to plaintiffs with respect to any such NDCs. To the extent the remaining allegations in Paragraph 1 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI expressly deny them. Ivax Corp. and IPI specifically deny that they have been involved in "fraudulent and misleading schemes" or that the New York State Medicaid Program has been "overcharge[d]" for prescription drugs. To the extent the remaining allegations in Paragraph 1 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

- 2. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 or the exhibit referenced therein, and therefore deny them. To the extent the allegations in Paragraph 2 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 3. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 or its footnote, and therefore deny them, except admit that it pays Medicaid rebates to the State of New York and that such rebates lower the price New York Medicaid pays for Ivax Corp.'s and IPI's prescription drugs. To the extent the allegations in Paragraph 3 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 4. To the extent the allegations in Paragraph 4 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 4 are directed at parties

other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

5. To the extent the allegations in Paragraph 5 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Ivax Corp. and IPI otherwise lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5, and therefore deny them.

- 6. To the extent the allegations in Paragraph 6 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Ivax Corp. and IPI otherwise lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 or its footnote, except Ivax Corp. and IPI specifically deny that they "actively encourage[s] physicians to write DAW in order to secure AWP-based reimbursement for pharmacies."
- 7. To the extent the allegations in Paragraph 7 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Ivax Corp. and IPI otherwise lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7, and therefore deny them.
- 8. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8, and therefore deny them.
- 9. To the extent the allegations in Paragraph 9 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. Ivax Corp. and IPI specifically deny that they "control and unlawfully inflates" average wholesale prices ("AWPs") or federal upper limits ("FULs"). To the extent the

allegations in Paragraph 9 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

- 10. To the extent the allegations in Paragraph 10 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them, except Ivax Corp. and IPI admit that they have provided the wholesale list price of its drugs to certain industry pricing compendia and that publishers apply their own markups to the list prices. Ivax Corp. and IPI specifically deny that they set AWPs. To the extent the allegations in Paragraph 10 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 11. To the extent the allegations in Paragraph 11 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 11 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 12. To the extent the allegations in Paragraph 12 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. Ivax Corp. and IPI specifically deny that they have reported "false and inflated" WACs, AWPs, or so-called "WAC equivalent[s]" to any industry pricing compendia. To the extent the allegations in Paragraph 12 or the exhibit referenced therein are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 13. To the extent the allegations in Paragraph 13 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them, except Ivax Corp. and IPI admit that CMS has established FULs

for certain drugs. Ivax Corp. and IPI specifically deny that they control "the FUL." To the extent the allegations in Paragraph 13 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 13 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

- 14. To the extent the allegations in Paragraph 14 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 14 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 15. To the extent the allegations in Paragraph 15 or the exhibit referenced therein are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 15 or the exhibit referenced therein are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 16. To the extent the allegations in Paragraph 16 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 16 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 17. To the extent the allegations in Paragraph 17 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 17 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

- 18. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18, and therefore deny them.
- 19. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18, and therefore deny them.
- 20. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20, and therefore deny them. To the extent the allegations in Paragraph 20 refer to a Wall Street Journal article, the article speaks for itself, and any characterizations thereof are denied.
- 21. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21 or the exhibit reference therein, and therefore deny them.
- 22. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 22, and therefore deny them.
- 23. To the extent the allegations in Paragraph 23 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 23 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 24. To the extent the allegations in Paragraph 24 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 24 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

- 25. To the extent the allegations in Paragraph 25 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 25 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 26. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26, and therefore deny them. To the extent the allegations in Paragraph 26 refer to a HHS OIG report, the report speaks for itself, and any characterizations thereof are denied.
- 27. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27, and therefore deny them. To the extent the allegations in Paragraph 27 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.
- 28. To the extent the allegations in Paragraph 28 or the exhibit referenced therein are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 28 or the exhibit referenced therein are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 29. To the extent the allegations in Paragraph 29 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 29 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

- 30. To the extent the allegations in Paragraph 30 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 30 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 31. To the extent the allegations in Paragraph 31 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. Ivax Corp. and IPI otherwise lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 or its footnote, and therefore deny them.
- 32. To the extent the allegations in Paragraph 32 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 32 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 33. To the extent the allegations in Paragraph 33 or its footnote are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 33 or its footnote are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraph 33 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 34. To the extent the allegations in Paragraph 34 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 34 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in

Paragraph 34 refer to a HHS OIG report, the report speaks for itself, and any characterizations thereof are denied.

- 35. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35, and therefore deny them.
- 36. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 36, and therefore deny them.
- 37. Ivax Corp. and IPI admit that the Counties seek the relief listed in Paragraph 37, but Ivax Corp. and IPI deny there is any basis for them to do so and deny that they are entitled to any relief. To the extent the remaining allegations in Paragraph 37 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 37 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 38. Ivax Corp. and IPI admit that the Counties seek to bring this action as alleged in Paragraph 38, but deny there is any basis for them to do so and deny that they are entitled to any relief.
- 39. Paragraph 39 states legal conclusions as to which no response is required. To the extent a response is deemed to be required, Ivax Corp. and IPI deny the allegations in Paragraph 39.
- 40. Paragraph 40 states legal conclusions as to which no response is required. To the extent a response is deemed to be required, Ivax Corp. and IPI deny the allegations in Paragraph

40, except admit that each of the captioned matters has been transferred to this Court by the Judicial Panel on Multi District Litigation pursuant to 28 U.S.C. 1407.

- 41. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41, and therefore deny them.
- 42. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 42 through 42 A, and therefore deny them.
- 43. Ivax Corp. and IPI deny the allegations in Paragraph 43 and its footnote, and refers to Case Management Order No. 33, dated September 14, 2007, ¶¶ 1, 3 for which plaintiffs are suing which defendants.
- 44. To the extent the allegations in Paragraph 44 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them, except admit that they manufacture and sell prescription drugs and transact business in the State and City of New York. To the extent the allegations in Paragraph 44 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 45-64. The allegations in Paragraphs 45-64 are directed to other defendants and require no response from Ivax Corp. or IPI. To the extent a response is deemed to be required, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 45-64, and therefore deny them.
- 65. Ivax Corp. and IPI admit that Ivax Corporation is a Florida corporation and admit its principal place of business, but deny that Ivax Corporation is engaged in the business of manufacturing and selling pharmaceuticals. Ivax Corp. and IPI admit that Ivax Pharmaceuticals

Inc. is a Florida corporation and admit its principal place of business. Ivax Corp. and IPI further admit Ivax Pharmaceuticals Inc. is engaged in the business of manufacturing and selling pharmaceuticals.

- 66-80. The allegations in Paragraphs 66-80, including subparts, are directed to other defendants and require no response from Ivax Corp. or IPI. To the extent a response is deemed to be required, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 66-84, and therefore deny them.
- 81. With respect to the allegations in Paragraph 81(a), Ivax Corp. and IPI admit that Teva Pharmaceuticals Industries, Ltd is an Israeli corporation and admit its principal place of business, but deny that it is engaged in the business of manufacturing and selling generic and proprietary branded pharmaceuticals and active pharmaceutical ingredients anywhere in the United States. Ivax Corp. and IPI admit the allegations of Paragraph 81(b). Ivax Corp. and IPI admit the allegations of Paragraph 81(c) with respect to Sicor's principal place of business, but deny the remaining allegations of Paragraph 81(c). Ivax Corp. and IPI deny the allegations of Paragraph 81(d).
- 82-84. The allegations in Paragraphs 82-84 are directed to other defendants and require no response from Ivax Corp. or IPI. To the extent a response is deemed to be required, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 82-84, and therefore deny them.
- 85-88. The allegations in Paragraphs 85-88 are directed to unknown defendants and require no response from Ivax Corp. or IPI. To the extent a response is deemed to be required, Ivax Corp. and IPI deny that it was involved any conspiracy related to drug pricing with either

named or unknown defendants. Ivax Corp. and IPI also deny that it has engaged in any "wrongful acts" related to drug pricing. To the extent the allegations of Paragraphs 85-88 refer to other known or unknown defendants, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 85-88, and therefore deny them.

- 89. With respect to the allegations in Paragraph 89, Ivax Corp. and IPI admit that Medicaid was established by Title XIX of the Social Security Act. Ivax Corp. and IPI further state that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.
- 90. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 90, and therefore deny them, except admit that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 90 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 91-99. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 91-99, and therefore deny them. To the extent the allegations in Paragraphs 91-99 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 100. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 100, and therefore deny them, except admit that national drug codes are assigned to prescription drugs and that the FOA assigns such codes.

- 101-111. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 101-111, and therefore deny them. To the extent the allegations in Paragraphs 101-111 or their footnotes refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 112. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 112, and therefore deny them, except admit that pricing compendia such as Blue Book publish AWPs and FULs. Ivax Corp. and IPI deny that they have any control over such prices.
- 113. To the extent the allegations in Paragraph 113 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent that the allegations of Paragraph 113 are directed to other defendants, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraph 113 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.
- 114. To the extent the allegations in Paragraph 114 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent that the allegations of Paragraph 114 are directed to other defendants, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraphs 114 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.
- 115. To the extent the allegations in Paragraph 115 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent that the allegations of Paragraph 115 are directed to other defendants, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as

to their truth, and therefore deny them. To the extent the allegations in Paragraphs 115 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

- 116-123. With respect to the allegations in Paragraphs 116-123 and their footnotes, Ivax Corp. and IPI admit that the Medicaid statute includes a rebate provision, that they have entered into rebate agreements with the Secretary of Health and Human Services, and that rebates help reduce state Medicaid drug expenditures. Ivax Corp. and IPI further state that the rebate provision speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 116-123 or their footnotes refer to additional statutes, regulations or congressional reports, those sources also speak for themselves, and any characterizations thereof are also denied.
- 124. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth of the allegations in Paragraph 124, and therefore deny them. To the extent the allegations in Paragraph 124 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 125. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth of the allegations in Paragraph 125, and therefore deny them. To the extent the allegations in Paragraph 125 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 126. With respect to the allegations in Paragraph 126, Ivax Corp. and IPI admit that drug manufacturers report Best Prices and AMPs to HHS. To the extent the allegations in Paragraph 126 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

- 127. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth of the allegations in Paragraph 127, and therefore deny them. To the extent the allegations in Paragraph 127 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 128. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth of the allegations in Paragraph 128, and therefore deny them. To the extent the allegations in Paragraph 128 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 129. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth of the allegations in Paragraph 129, and therefore deny them. To the extent the allegations in Paragraph 129 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 130. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth of the allegations in Paragraph 130, and therefore deny them.
- 131. To the extent the allegations in Paragraph 131 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 131 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraph 131 refer to the Model Rebate Agreement, that document speaks for itself, and any characterizations thereof are denied.

- 132. To the extent the allegations in Paragraph 132 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI admit that they have executed rebate agreements with HHS. Ivax Corp. and IPI further state that the rebate agreements speaks for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 132 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraph 132 refer to the Model Rebate Agreement, that document also speaks for itself, and any characterizations thereof are also denied.
- 133-136. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 133-136, and therefore deny them. To the extent the allegations in Paragraphs 133-136 refer to the Model Rebate Agreement, that document speaks for itself, and any characterizations thereof are denied.
- 137-143. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 137-143, and therefore deny them. To the extent the allegations in Paragraphs 137-143 refer to statutes, regulations or any other documents, those sources speak for themselves, and any characterizations thereof are denied.
- 144. To the extent the allegations in Paragraph 144 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 144 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 145-149. Ivax Corp. and IPI admit that Exhibit B purports to identify the prescription drugs at issue, but deny the accuracy of the data listed therein. To the extent the

remaining allegations in Paragraph 145-149 or Exhibit B are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the remaining allegations in Paragraphs 145-149 or Exhibit B are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

- 150-153. To the extent the allegations in Paragraphs 150-153 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 150-153 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 154. Paragraph 154 purports to contain a statement from HHS OIG, but Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to its accuracy because the source thereof is not provided, and therefore deny the allegations of Paragraph 154. To the extent the source of the statement is provided, the source speaks for itself, and any characterizations thereof are denied.
- 155-158. To the extent the allegations in Paragraphs 155-158 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. Ivax Corp. and IPI further state that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices reported to industry compendia. To the extent the allegations in Paragraphs 155-158 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 159-165. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 159-165, except admit that PBMs are

involved in administering and managing prescription drug benefit programs and that certain PBMs also operate mail order pharmacies. To the extent the allegations in Paragraphs 159-165 refer to articles or reports, those sources speak for themselves, and any characterizations thereof are denied.

- 166. To the extent the allegations in Paragraph 166 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. Ivax Corp. and IPI specifically deny that they "control the published reimbursement prices." To the extent the allegations in Paragraph 166 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 167. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 167, and therefore deny them.
- Corp. or IPI, Ivax Corp. and IPI deny them, except admit that they have executed rebate agreements with HHS. Ivax Corp. and IPI further state that the rebate agreements speaks for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 168-172 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraphs 168-172 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 173-176. To the extent the allegations in Paragraphs 173-176 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 173-176 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or

information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraphs 173-176 refer to statutes, regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

- 177-194. To the extent the allegations in Paragraphs 177-194 or their footnotes are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 178-194 or their footnotes are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraphs 177-194 or their footnotes refer to reports, articles, letters, congressional hearing transcripts, or other documents, those sources speak for themselves, and any characterizations thereof are denied.
- 195. To the extent the allegations in Paragraph 195 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them, except admit that contracts with purchasers sometimes included discounts. To the extent the allegations in Paragraph 195 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.
- 196. To the extent the allegations in Paragraph 196 or the exhibit referenced therein are directed at Ivax Corp. and IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraph 196 or the exhibit referenced therein are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

197-508. The allegations in Paragraphs 197-508 are directed to other defendants and require no response from Ivax Corp. or IPI. To the extent a response is deemed to be required,

Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 197-508, and therefore deny them.

- 509. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 509 or its footnote or the exhibit referenced therein, and therefore deny them. Ivax Corp. and IPI deny that they have engaged in any "fraud," and state that Exhibits A and B to the RFACC have changed since the filing of plaintiffs' RFACC.
- 510. Ivax Corp. and IPI deny the allegations in Paragraph 510 and the exhibit referenced therein, and therefore deny them, and state that Exhibits A and B to the RFACC have changed since the filing of the RFACC.

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- 511. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 511, and therefore deny them, except Ivax Corp. and IPI specifically deny reporting "intentionally false and misleading AWP[s]" or "false and misleading wholesale price information." Further, Ivax Corp. and IPI specifically deny engaging in any "fraud."
- 512. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 512, and therefore deny them, except Ivax Corp. and IPI specifically deny reporting "intentionally false and misleading AWP[s]" or "false and misleading wholesale price information." Further, Ivax Corp. and IPI specifically deny engaging in any "fraud."
- 513. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 513, and therefore deny them, except Ivax Corp. and IPI

specifically deny reporting "intentionally false and misleading AWP[s]." Further, Ivax Corp. and IPI specifically deny engaging in any "fraud."

- 514. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 514, and therefore deny them, except Ivax Corp. or IPI specifically deny any "failure to account for [] deeply discounted contract prices" or that their conduct resulted in any "FUL being false and inflated." Further, Ivax Corp. and IPI specifically deny engaging in any "fraud."
- 515. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 515, and therefore deny them.
- 516. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 516, and therefore deny them, except Ivax Corp. or IPI specifically deny any "failure to report accurate price information resulting in a fraudulent FUL and damage to the County Medicaid Programs." Further, Ivax Corp. and IPI specifically deny engaging in any "fraud."
- 517. Ivax Corp. and IPI deny the allegations of Paragraph 517, except admit that Ivax Pharmaceuticals, Inc. and/or Ivax Corp. have been named as defendants in lawsuits filed by the states of Florida, Illinois, Kentucky, Massachusetts, and Wisconsin. Ivax Corp. and IPI specifically deny that there is any basis for those lawsuits or that they have been involved in any "wrongdoing."
- 518-519. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraphs 518-519, and therefore deny them.

- 520. Ivax Corp. and IPI deny the allegations of Paragraph 520, except admit that they have made disclosures regarding certain investigations involving pharmaceutical industry pricing practices. To the extent Paragraph 520 refer to Securities and Exchange Commission filings, the filings speak for themselves, and any characterizations thereof are denied.
- 521. Ivax Corp. and IPI deny the allegations of Paragraph 521, except admit that IPI has been named as a defendant in lawsuits filed by the states of Massachusetts, Florida, Illinois, Wisconsin, Kentucky, Alabama, and Nevada. Ivax Corp. and IPI specifically deny that there is any basis for those lawsuits or that they have been involved in any "wrongdoing." To the extent Paragraph 521 refer to Securities and Exchange Commission filings, the filings speak for themselves, and any characterizations thereof are denied.

- 522. Ivax Corp. and IPI deny the allegations of Paragraph 522, except admit that they have made disclosures regarding certain investigations involving pharmaceutical industry pricing practices, involving IPI. To the extent Paragraph 522 refer to Securities and Exchange Commission filings, the filings speak for themselves, and any characterizations thereof are denied.
- 523. Ivax Corp. and IPI deny the allegations of Paragraph 523, except admit that the Massachusetts Attorney General's office served a subpoena for documents on Ivax Corp.
- 524. Ivax Corp. and IPI deny the allegations of Paragraph 524, except admit that Ivax Corp. has been named in a lawsuit filed by the Massachusetts Attorney General.
- 525. Ivax Corp. and IPI deny the allegations of Paragraph 525, and specifically deny that Ivax Corp. or IPI reported "inflated wholesale price information," "underreport[ed] []

AMP," or submitted "fraudulent AMP and AWP data." Further, Ivax Corp. and IPI specifically deny that the Counties have been damaged by Ivax Corp. or IPI.

526-769. The allegations in Paragraphs 526-769 are directed to other defendants and require no response from Ivax Corp. or IPI. To the extent a response is deemed to be required, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 526-769, and therefore deny them.

770-772. To the extent the allegations in Paragraphs 770-772 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations that the Counties' Medicaid programs "spent over \$20 billion for defendants' drugs from 1992 – 2005," and therefore deny them on that basis. Ivax Corp. and IPI specifically deny that they were involved in any "false price reporting scheme" or "misconduct," or that they have been "unjustly enriched." To the extent the allegations in Paragraphs 770-772 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

773-790. To the extent the allegations in Paragraphs 773-790 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. Ivax Corp. and IPI further state that for years, and at all times relevant to the RFACC, it has been common knowledge and universally understood, including by the Counties and/or their agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 773-790 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent

the allegations in Paragraph 786 refer to *The Pink Sheet*, that document speaks for itself, and any characterizations thereof are denied.

## **COUNT I**

# VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)

791. In response to Paragraph 791, Ivax Corp. and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 790.

792-800. To the extent the allegations in Paragraphs 792-800 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI state that the Court has dismissed them. To the extent that a response is still required, Ivax Corp. and IPI deny the allegations. To the extent the allegations in Paragraphs 792-800 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

## **COUNT II**

# VIOLATION OF N.Y. SOCIAL SERVICES LAW 367-a(7)(d) (FAILURE TO COMPLY WITH STATE MEDICAID REBATE PROVISION)

801. In response to Paragraph 801, Ivax Corp. and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 800.

802-807. To the extent the allegations in Paragraphs 802-807 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI state that the Court has dismissed them. To the extent that a response is still required, Ivax Corp. and IPI deny the allegations. To the extent the allegations in Paragraphs 802-807 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

#### **COUNT III**

# VIOLATION OF NEW YORK SOCIAL SERVICES LAW 145-b (OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS)

- 808. In response to Paragraph 808, Ivax Corp. and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 807.
- 809. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 809, and therefore deny them. To the extent the allegations in Paragraph 809 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

810-813. To the extent the allegations in Paragraphs 810-813 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 810-813 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraphs 810-813 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 810-813 contain legal conclusions, no response is required.

#### **COUNT IV**

# VIOLATION OF NEW DEPARTMENT OF HEALTH REGULATIONS 18 N.Y.C.R.R. 512.2(b)4) and (5)

- 814. In response to Paragraph 814, Ivax Corp. and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 813.
- 815-817. To the extent the allegations in Paragraphs 815-817 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI state that the Court has dismissed them. To the extent that a response is still required, Ivax Corp. and IPI deny the allegations. To the extent the allegations in

Paragraphs 815-817 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

## **COUNT V**

#### **BREACH OF CONTRACT**

818. In response to Paragraph 818, Ivax Corp. and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 817.

819-830. To the extent the allegations in Paragraphs 819-830 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI state that the Court has dismissed them. To the extent that a response is still required, Ivax Corp. and IPI deny the allegations. To the extent the allegations in Paragraphs 819-830 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

#### **COUNT VI**

# UNFAIR TRADE PRACTICES (Violations of N.Y. Gen. Bus. Law 349 et seq.)

- 831. In response to Paragraph 831, Ivax Corp. and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 830.
- 832-835. To the extent the allegations in Paragraphs 832-835 and the exhibits referenced therein are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 832-835 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraphs 832-835 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

836-837. To the extent the allegations in Paragraphs 836-837 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 836-837 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraphs 836-837 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

838-839. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 838-839 and the sub-parts thereto contain legal conclusions, no response is required.

#### **COUNT VII**

## FRAUD

- 840. In response to Paragraph 840 Ivax Corp. and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 839.
- 841-843. To the extent the allegations in Paragraphs 841-843 and the exhibits referenced therein are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 841-843 are directed at parties other than Ivax Corp. or IPI, Ivax Corp.

and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them.

- 844. Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 844, and therefore deny them. To the extent the allegations in Paragraph 844 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.
- 845. To the extent the allegations in Paragraph 845 are directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 845 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraph 845 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 845 contain legal conclusions, no response is required.

#### **COUNT VIII**

## **UNJUST ENRICHMENT**

- 846. In response to Paragraph 846, Ivax Corp. and IPI repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 845.
- 847-849. To the extent the allegations in Paragraphs 847-849 directed at Ivax Corp. or IPI, Ivax Corp. and IPI deny them. To the extent the allegations in Paragraphs 847-849 are directed at parties other than Ivax Corp. or IPI, Ivax Corp. and IPI lack knowledge or information

sufficient to form a belief as to their truth, and therefore deny them. To the extent the allegations in Paragraphs 847-849 contain legal conclusions, no response is required.

850-858. Ivax Corp. and IPI deny that the Counties are entitled to a judgment or any other relief as requested in the unnumbered "WHEREFORE" paragraph and Paragraphs 850-858 of the RFACC.

WHEREFORE, Ivax Corp. and IPI demand judgment dismissing the RFACC with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

#### **AFFIRMATIVE DEFENSES**

Ivax Corp. and IPI, without assuming any burden that they would otherwise bear, assert the following affirmative defenses:

## **First Affirmative Defense**

Plaintiff fails to state a claim against Ivax Corp. and IPI upon which relief may be granted.

## **Second Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because they did not rely on any alleged misrepresentations or fraud by Ivax Corp. and IPI. Plaintiffs knew that providers could obtain Ivax Corp. and IPI drugs at prices below AWP prior to the relevant time period stated in the RFACC.

## **Third Affirmative Defense**

Plaintiffs' claim is barred, in whole or in part, by the political question and separation of powers doctrines.

## **Fourth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the filed rate doctrine.

# Fifth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the state action doctrine.

# **Sixth Affirmative Defense**

To the extent Plaintiffs or the State of New York obtain recovery in any other case predicated on the same factual allegations, Plaintiffs are barred from seeking recovery against Ivax Corp. and IPI based on the RFACC pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

## **Seventh Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Ivax Corp. and IPI in judicial, legislative, or administrative proceedings of any kind or at any level of government.

## **Eighth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiffs' claims.

## **Ninth Affirmative Defense**

Plaintiffs' state law claims are preempted, in whole or in part, by federal law, including without limitation the dormant Commerce Clause, and by the Commerce Clause of the United States Constitution, the Federal Employment Retirement Income and Security Act of

1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

## **Tenth Affirmative Defense**

Plaintiffs' claims against Ivax Corp. and IPI are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

## **Eleventh Affirmative Defense**

Plaintiffs fail to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against Ivax Corp. and IPI contained in the RFACC.

# **Twelfth Affirmative Defense**

Any and all actions taken by Ivax Corp. and IPI with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

## Thirteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because plaintiffs' alleged injuries and damages were not legally or proximately caused by any acts or omissions of Ivax Corp. or IPI and/or were caused, if at all, by the conduct of plaintiffs and/or third parties.

## **Fourteenth Affirmative Defense**

Ivax Corp. and IPI deny that Plaintiffs have valid consumer protection claims against Ivax Corp. and IPI under New York's Unfair Trade Practices Act. However, if such claims are found to exist, Ivax Corp. and IPI plead all available defenses under the Act.

## Fifteenth Affirmative Defense

To the extent that Plaintiffs attempt to seek equitable relief against Ivax Corp. and IPI, Plaintiffs are not entitled to such relief because Plaintiffs have an adequate remedy at law.

## **Sixteenth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs would be unjustly enriched if allowed to recover any portion of the damages alleged in the RFACC.

## **Seventeenth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiffs have received and paid for medicines manufactured, marketed and sold by Ivax Corp. and IPI after the filing of the complaint of Suffolk County.

# **Eighteenth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

## **Nineteenth Affirmative Defense**

Plaintiffs' claims against Ivax Corp. and IPI are barred, in whole or in part, due to their failure to join indispensable parties.

## **Twentieth Affirmative Defense**

Plaintiffs' claims against Ivax Corp. and IPI are barred, in whole or in part, because Plaintiffs have not suffered damages as a result of the matters alleged in the RFACC.

## **Twenty-First Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs failed to mitigate damages, and that failure to mitigate damages should proportionately reduce Plaintiffs' recovery and the allocation of any fault, if any exists, attributable to Ivax Corp. and IPI.

#### **Twenty-Second Affirmative Defense**

Ivax Corp. and IPI are entitled to a set-off, should any damages be awarded against them, for the entire amount of all damages or settlement amounts recovered by Plaintiffs, with respect to the same alleged injuries.

#### **Twenty-Third Affirmative Defense**

To the extent punitive damages are sought, plaintiffs' claims for punitive damages against Ivax Corp. and IPI cannot be sustained because an award of punitive damages by a jury that (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Ivax Corp. or IPI; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding plaintiffs' burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Ivax Corp.'s and IPI's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law, and public policies of the State of New York.

## **Twenty-Fourth Affirmative Defense**

To the extent punitive damages are sought, plaintiffs' punitive damages claims against Ivax Corp. and IPI (1) have no basis in law or fact; (2) are not recoverable because the allegations of the RFACC are legally insufficient to support a claim for punitive damages against Ivax Corp. or IPI; (3) cannot be sustained because the laws regarding the standards for determining liability for and the amount of punitive damages fail to give Ivax Corp. or IPI prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed, and are void for vagueness in violation of Ivax Corp.'s and IPI's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of New York; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the criminal laws or other laws would violate Ivax Corp.'s and IPI's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law and law of the State of New York; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Ivax Corp. or IPI for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Ivax Corp.'s or IPI's products would constitute impermissible multiple punishments for the same wrong, in violation of Ivax Corp.'s and IPI's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law, and statutory laws of the State of New York; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint

tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Ivax Corp.'s and IPI's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of New York; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according Ivax Corp. and IPI the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Ivax Corp.'s and IPI's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law, and public policies of the State of New York.

## **Twenty-Fifth Affirmative Defense**

Ivax Corp. and IPI adopt by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

#### **Twenty-Sixth Affirmative Defense**

Plaintiffs and/or their agents knew and were aware that AWP did not and was not intended to reflect either an actual average of wholesale prices or actual acquisition costs. Legal and equitable principles preclude this action for damages and injunctive relief, and the Due Process Clause of the United States Constitution and the New York Constitution preclude plaintiff from bringing claims and seeking damages as alleged in the RFACC.

#### **Twenty-Seventh Affirmative Defense**

The claims alleged herein, based on the facts alleged, are barred by plaintiffs' own negligence or gross negligence.

## Twenty-Eighth Affirmative Defense

Plaintiffs' reimbursement rates for drugs for Medicaid recipients were filed with, reviewed, and approved by a federal regulatory agency with authority to do so under the Medicaid Act. Actions in seeking relief, including alleged damages, contending that rates approved by a federal regulatory agency do not apply or are not binding are, as the United States Supreme Court directed, precluded by the Supremacy Clause. This action is barred by the Supremacy Clause of the Constitution.

## **Twenty-Ninth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because they have no standing or capacity to bring some or all of the claims raised in this suit.

# **Thirtieth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because the alleged conduct was reasonable and based on independent, legitimate business and economic justifications.

# **Thirty-First Affirmative Defense**

Any and all actions taken by Ivax Corp. and IPI with respect to any of the matters alleged in the RFACC were lawful, justified, pro-competitive, carried out in furtherance of both Ivax Corp.'s and IPI's legitimate business interests, and constitute *bona fide* business competition.

## **Thirty-Second Affirmative Defense**

To the extent punitive damages are sought, plaintiffs' claims for punitive damages against Teva cannot be sustained because an award of punitive damages that is not subject to a reasonable limit and specific standards, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would (1) violate Ivax Corp.'s and IPI's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Ivax Corp.'s and IPI's right not to be subjected to an excessive

award; and (3) be improper under the Constitution, common law, and public policies of the State of New York.

## **Thirty-Third Affirmative Defense**

Plaintiffs' claims against Ivax Corp. and IPI are barred, in whole or in part, because Ivax Corp. and IPI did not make any false statements to plaintiffs or their agents. As to any statement asserted against Ivax Corp. and IPI that plaintiffs alleges to be false or misleading, Ivax Corp. and IPI had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

## **Thirty-Fourth Affirmative Defense**

Plaintiffs did not reasonably rely on any allegedly fraudulent statements, conduct, or omissions by Ivax Corp. or IPI.

# **Thirty-Fifth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because they violate Ivax Corp.'s and IPI's rights under the Due Process and *Ex Post Facto* Clauses of the United States Constitution, as well as the Constitution of the State of New York, insofar as plaintiffs seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

#### **Thirty-Sixth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of New York.

#### **Thirty-Seventh Affirmative Defense**

Plaintiffs' claims for injunctive relief against Ivax Corp. and IPI are barred by the doctrines of *in pari delicto* and/or unclean hands.

## **Thirty-Eighth Affirmative Defense**

Plaintiffs' claims against Ivax Corp. and IPI for injunctive relief were mooted by the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

## **Thirty-Ninth Affirmative Defense**

Teva Pharmaceuticals, USA has affirmatively stated on its published price lists that the AWP reported on its lists was only a "suggested" AWP. Accordingly, plaintiffs are estopped from claiming to have been defrauded by virtue of any action by it.

## **Fortieth Affirmative Defense**

Plaintiffs' claims against Teva are misjoined with plaintiffs' claims against other defendants and must be severed.

## **Forty-First Affirmative Defense**

Plaintiffs claims against Teva are barred in whole or in part by the existence and terms of the written rebate agreements between Ivax Corp. and IPI and the Secretary of the Department of Health and Human Services ("HHS"), on behalf of HHS and States including New York, entitled "Rebate Agreement between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement," which was entered into pursuant to 42 U.S.C. § 1396r-8.

# **Forty-Second Affirmative Defense**

Plaintiffs have failed to exhaust available statutory and administrative remedies.

#### **Forty-Third Affirmative Defense**

Plaintiffs have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Ivax Corp. or IPI as alleged in the RFACC.

## Forty-Fourth Affirmative Defense

Plaintiffs fail to allege facts or a cause of action against Ivax Corp. or IPI sufficient to support a claim for prejudgment interest or any other relief.

## **Forty-Fifth Affirmative Defense**

Any damages recovered by the plaintiff from Teva must be limited by the applicable statutory ceilings on recoverable damages.

## Forty-Sixth Affirmative Defense

Plaintiffs' unjust enrichment claims and prayers for relief in the form of restitution are barred, in whole or in part, because Ivax Corp. and IPI did not retain any money belonging to the Plaintiffs as a result of any alleged overpayments as required under New York law.

## Forty-Seventh Affirmative Defense

To the extent plaintiffs' claims would result in Teva paying damages to more than one claimant for the same alleged overcharge, they are barred because such multiple liability would violate rights guaranteed to Ivax Corp. and IPI by the United States Constitution, including, without limitation, rights guaranteed under the Due Process Clause of the Fourteenth Amendment.

# Forty-Eighth Affirmative Defense

Plaintiff fails to allege facts or a cause of action against Teva sufficient to support a claim for compensatory damages, attorneys' fees and/or legal fees, or any other relief.

## **Forty-Ninth Affirmative Defense**

Plaintiffs' unjust enrichment claims and prayers for relief in the form of restitution are barred, in whole or in part, because Ivax Corp. and IPI did not retain any money belonging to the Plaintiffs as a result of any alleged overpayments as required under New York law.

## **CONCLUSION**

Ivax Corp. and IPI reserve the right to amend this Answer and to assert other defenses as this action proceeds.

WHEREFORE, Ivax Corp. and IPI deny that the plaintiffs are entitled to any relief whatsoever and respectfully requests judgment dismissing the RFACC with prejudice, and with costs and fees, as may be allowed by law, and such further relief as the Court deems appropriate.

Dated this 26th day of October, 2007.

Respectfully submitted,

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Counsel for Defendants Ivax Corporation and Ivax Pharmaceuticals, Inc.

# **CERTIFICATE OF SERVICE**

I hereby certify that on this 26th day of October 2007 a true and correct copy of the foregoing pleading was electronically served on all counsel of record by transmission to Lexis Nexis File & Serve.

Attorneys for Defendants Teva

 ${\it Pharmaceuticals~USA, Inc.~and~Sicor,}$ 

Inc.